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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,663

10/24/2003

Gene DiPoto

ENDIUS.033A

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11/17/2006

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,663

Applicant(s)

DIPOTO, GENE

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/24/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18, and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison (US Patent 6,530,926) in view of Cornwall et al. (US Patent 6,485,518).

Davison discloses a method of securing vertebrae including the steps of inserting in a patient an access device (see Fig. 5, item 10, and Col. 2, lines 58-63), where the access device has a first and second configuration (see Col. 3, lines 3-39) that has an enlarged cross sectional area (see Fig. 1), and wherein through the access device, a fastener can be inserted to fasten vertebrae. The device is actuated from the first to second position using the expansion tool (112) and manual force and wherein the second position is considered substantially perpendicular to the spine of the patient. Further Davison discloses a method wherein the method is generally a posterior (see Fig. 5) or posterolateral approach (See Col. 12, lines 44-48), a method that has a boring tool to yield access to the vertebrae (note Davidson refers to the action of creating holes as drilling, but is regarded as a step capable of "boring" holes in preparation for the vertebral fasteners), preventing movement of the first vertebra in relation to the second via two fixation elements (650) into the cannula (see Col. 13, lines 18-22), wherein the

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same access device may be used for the second fastener.

Davison discloses the claimed method except for the step of delivering a fastener(s) through a first vertebra and into a second vertebra while providing transfacet fixation keeping the vertebrae from moving relative to one another and also wherein the second vertebra is considered adjacent in the working space. Cornwall et al. disclose an intervertebral support and fusion system that allows for transfacet fixation using a fastener (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See also Cols. 1 and 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device and perform the method of Davison having at least the step of delivering a fastener(s) through a first vertebra and into a second vertebra while providing transfacet fixation keeping the vertebrae from moving relative to one another and also wherein the second vertebra is considered adjacent in the working space in view of Cornwall et al. to better use the device to secure vertebrae.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Davison '926 and Cornwall et al. '518 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Davison '926 and Cornwall et al. '518 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener

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or securing device is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of the combination of Davison '926 and Cornwall et al. '518 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Davison '926 and Cornwall et al. '518. The combination of Davison '926 and Cornwall et al. '518 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posterally through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

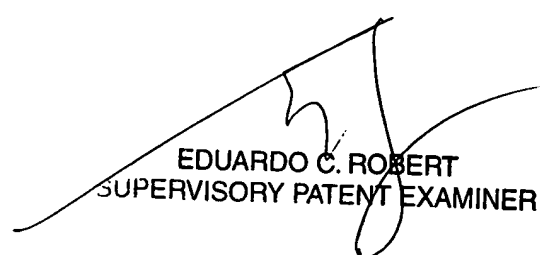
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



11/11/2006

JLS



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER